K123535

JAN 15 2013

Boston Scientific

510(k) Summary of Safety and Effectiveness
Boston Scientific Corporation
iLab™ Ultrasound Imaging System

General Information

Manufacturer:

Boston Scientific Corporation
47215 Lakeview Boulevard
Fremont, CA 94538

Establishment Registration Number: 2939204

Contact Person:

Lori R. Smith
Sr. Regulatory Affairs Specialist
Tel: (510) 624-1698
Fax: (510) 624-2569
lori.smith@bsci.com

Date Prepared: November 15, 2012

Device Description

Classification Name(s):

Class II
Ultrasonic Pulsed Echo Imaging System
21 CFR Part 892.1560 (90IYO)
Transducer, Ultrasonic, Diagnostic
21 CFR Part 892.1570 (90ITX)

Trade Name: iLab™ Ultrasound Imaging System

Generic/Common Name:

Ultrasound Diagnostic Imaging System
Ultrasonic Pulsed Echo Imaging System (90IYO)
Transducer, Ultrasonic, Diagnostic
(90ITX)

Predicate Devices

iLab Ultrasound Imaging System K072517

Intended Uses/Indications for Use

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

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Product Description

The iLab Ultrasound Imaging System is designed for real time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures.

Technology

The modified iLab Ultrasound Imaging System employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence

Summary of Non-Clinical Tests:

Non-clinical data, which includes software verification and validation has been evaluated as detailed in Section VI of this premarket notification. Software unit and system level verification testing demonstrate that the iLab 2.7.1 update meets the acceptance criteria as noted in the iLab System Software Unit and System Test Plans. All requirements in the Software Requirements Specifications have been verified by the system level testing. Validation was performed by testers with clinical experience evaluating IVUS images. Validation passed its acceptance criteria in that a majority of the validation test results demonstrate that iLab 2.7.1 image quality is equivalent or better than the predicate device.

Summary of Clinical Tests:

The modified iLab Ultrasound Imaging System did not require clinical studies to support substantial equivalence.

Conclusion

The proposed modifications to the iLab Ultrasound Imaging System described in this submission are substantially equivalent to the predicate device. The proposed modification in software and labeling are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Lori R. Smith
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
47215 Lakeview Boulevard
FREMONT CA 94538

January 15, 2013

Re: K123535
Trade/Device Name: iLab™ Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: December 18, 2012
Received: December 19, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123535

Device Name: iLab™ Ultrasound Imaging System

Indications for Use:

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123535